UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,755	09/28/2001	David P. Andrew	1855.1064-010	7274

21005 7590 01/28/2004

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
NOLAN, PATRICK J	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,755	ANDREW ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-28 and 50-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28 and 50-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 25-28 and 50-96 are pending.

2. Applicant's election of a test agent that is an organic compound and TECK, as a ligand or promoter in the Paper received 11-5-2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant is advised that the search has been extended to encompass all species, no art having been identified.

3. Claims 25-28 and 50-96 are under consideration in the instant application.

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. Applicant is requested to update the status of all related US applications on page of the specification.

Claim Rejections - 35 USC § 112 second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 25-28 and 50-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25, 60, 73, and 86 are ambiguous in reciting a "a cellular response" because the metes and bounds of what is a "response" are not defined. It is suggested that Applicant amend the claims to recite particular testable cellular responses.

In all the base claims Applicant refers to both "GPR-9-6 receptor" and GPR-9-6", when reading the specification it is clear GPR-9-6 is a receptor. It is suggested Applicant maintain consistent scientific terminology throughout the claims. Either the GPR-9-6 receptor or GPR-9-6.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 112 first paragraph

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 25-28 and 50-96 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following written description rejection is set forth herein.

The claims recite either singly or in combination a "mammalian GPR-9-6"; a "functional variant" of GPR-9-6; a "test agent" which inhibits ligand or promoter induced response via GPR-9-6; and a "ligand or promoter" of GPR-9-6 as part of the invention.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

However, there does not appear to be an adequate written description in the specification as-filed of any essential structural feature common to molecules that are "mammalian GPR-9-6"or a "functional variant" of GPR-9-6. Neither does there appear to be an adequate written description in the specification as-filed of any essential structural feature common to molecules that are a "test agent" which inhibits GPR-9-6 ligand or promoter induced response or "ligands or promoters" of GPR9-6 that identifies molecules as having the function of binding GPR9-6.

The specification discloses the human GPR-9-6 protein of SEQ ID NO:2 and bound by the 3C3 antibody. However, the instant claims are drawn to a large genus of GPR-9-6 molecules from any mammal (a "mammalian GRP9-6") or any "function variant" thereof. There does not appear to be any particular structure that must be shared by polypeptides in order to identify them as a "mammalian GPR9-6" or a "function variant" thereof. Thus the disclosure of a single species does not appear to provide adequate written support for the genus of "mammalian GPR9-6"

proteins or for the genus of a "function variant" of a mammalian GPR-9-6 protein that binds TECK.

Two species of a "test agent" which binds GPR-9-6 are disclosed in the specification: the chemokine TECK and antibodies which bind the human GPR-9-6 polypeptide of SEQ ID NO:2. The genus of "test agents" which bind GPR-9-6 encompasses any agent with the function of binding GPR-9-6. In addition, in many of the claims the reference agent may bind any mammalian GPR-9-6 protein or function variant thereof, as long as it also binds TECK. Thus the genus of "test agents" is extensive and highly variable and the disclosure of two species does not appear to be representative of the genus.

Similarly, the specification discloses a single chemokine ligand of GPR-9-6: TECK (see page 47 of the specification). However, the genus of molecules encompassed by the term "ligand or promter" is very large and includes not only chemokines and antibodies to GPR-9-6, but any molecule or pathogen which can bind GPR-9-6. Thus the disclosure of a single species of chemokine ligand does not appear to provide an adequate written description of the genus of "ligands or promoter of GPR-9-6".

Consequently, Applicant was not in possession of the instant claimed invention. See also Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Alternatively, Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

8. Claim 25-28 and 50-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 25-28 and 50-96, the specification gives insufficient guidance on how to make the test agents. While it is true one of skill in the art knows generically how to make a peptide or a nucleic acid or an antibody or generically any organic molecule, what is at issue is what guidance does the specification provide as to what the initial specific structure any of these compounds will have. How does one of skill in the art practice the invention when is essence the starting material could be any organic molecule known to science, or potentially synthetically made by science. This limitless amount of starting material combined with the lack of guidance

as to what particular structure a potential test agent would start out with would lead one of skill in the art with an undue amount of experimentation to practice the claimed invention.

9. Claims 53, 64, 77 and 89 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the MOLT-13 cell line is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent cell line. See 37 CFR 1.801-1.809.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

10. In claims 53, 64, 77 and 89, it is apparent that the MOLT-4 cell line is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell line. See 37 CFR 1.801-1.809.

However, it is noted that Applicant has indicated on page 20 of the specification that the MOLT-4 cell line is publicly available from the ATCC under ATCC Accession No. CRL-1582 (ATCC Cell Lines and Hybridomas, page 149, 7th edition, 1992 American Type Culture Collection, current address 10801 University Boulevard, Manassas, VA 20110-2209).

Therefore, the enablement requirement under 35 USC 112, first paragraph is considered to be fulfilled with respect to the MOLT-4 cell line.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

12. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
January 25, 2004